

K962575



Diagnostics

JUL 22 1996

510(k) Summary

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1. Submitter name, address, contact Boehringer Mannheim Corporation
2400 Bisso Lane
Concord, CA 94524-4117
(510) 674-0667

Contact Person: Patricia Klimley

Date Prepared: June 28, 1996

2. Device name Proprietary name: Elecsys® PreciControl Cardiac 1 and 2
Common name: Control material
Classification name: Enzyme controls (Assayed and Unassayed)

3. Predicate device The Boehringer Mannheim Elecsys® PreciControl Cardiac 1 and 2 are substantially equivalent to the Elecsys® CK-MB and Elecsys® Troponin-T CalSets (K961501 & K961500). The intended use has been changed to a quality control material.

Continued on next page



510(k) Summary, Continued

**4.
Device
Description**

Human serum albumin control with CK-MB and Troponin-T for use in CK-MB and Troponin-T assays.

**5.
Intended
use**

Control for Elecsys® CK-MB and Troponin-T assays.

**6.
Comparison
to
predicate
device**

The Boehringer Mannheim Elecsys® PreciControl Cardiac 1 and 2 are substantially equivalent to the Elecsys® CK-MB and Elecsys® Troponin-T CalSets (K961501 & K961500). The intended use has been changed to a quality control material.

The following table compares the Elecsys® PreciControl Cardiac 1 and 2 with the predicate device, Elecsys® CK-MB and Elecsys® Troponin-T CalSets (K961501 & K961500).

Similarities:

- Same matrix: Human serum matrix
 - Same analytes: CK-MB and Troponin-T
 - Standardization: CK-MB - commercially available CK-MB test, Troponin-T - highly purified bovine cardiac troponin-T.
 - Storage conditions: 2 - 8°C
 - Application test system: Elecsys® 2010
 - Reconstitution: 2 mL distilled water
 - Manufacturer: Boehringer Mannheim Germany
-

Continued on next page

510(k) Summary, Continued

**6.
Comparison
to
predicate
device cont.**

Differences:

Feature	Elecsys® CK-MB and Troponin-T CalSet	Elecsys ® PreciControl Cardiac
Target concentration	CK-MB: 0.15 and 500 ng/mL (approximately) Troponin-T: 0.021 and 25 ng/mL (approximately)	CK-MB: 6.0 and 60 ng/mL (approximately) Troponin-T: 0.2 and 6.0 ng/mL (approximately)
Intended Use	Calibration of the Elecsys CK-MB and Troponin-T Assays	Monitoring assays for CK-MB and Troponin-T
Open vial stability	2 weeks at 2 - 8°C	3 days at 2 - 8°C

Performance Characteristics:

Feature	Elecsys® CK-MB and Troponin-T CalSet	Elecsys ® PreciControl Cardiac
Open Vial Stability	2 weeks at 2 - 8°C	3 days at 2 - 8°C
Value Assignment	CK-MB: 0.15 and 500 ng/mL (approximately) Troponin-T: 0.021 and 25 ng/mL (approximately)	CK-MB: 6.0 and 60 ng/mL (approximately) Troponin-T: 0.2 and 6.0 ng/mL (approximately)